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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,796	01/11/2002	Naida M. Loskutoff	13511.1USU1	8344
23552	7590	02/16/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			AFREMOVA, VERA	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/044,796	<b>Applicant(s)</b> LOSKUTOFF ET AL.	
	<b>Examiner</b> Vera Afremova	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,9-11,13,14,21,22,24-26,28-31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,9-11,13,14,21,22,24-26,28-31,33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 2, 4-6, 9-11, 13, 14, 21, 22, 24-26 and 28-31 as amended and new claims 33 and 34 (11/07/2005) are pending and under examination.

#### ***Claim Rejections - 35 USC § 112***

Claims 1, 2, 4-6, 9-11, 13, 14, 21, 22, 24-26, 28-31, 33 and 34 (as amended and new) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 9, 10, 21, 33 and 35 (as amended and new) presently require “anionic” surfactant(s) that would be the same specific surfactant(s) as were listed in the original claims including polyoxyethylene sorbitan (claim 10) and some others (claim 9). However, accordingly to the applicants’ specific definitions as disclosed in the as-field specification the claimed “polyoxyethylene sorbitan”, “polyglycerol esters”, “glycerol esters”, “sorbitan esters” are nonionic surfactants (page 6, line 13-17) but not “anionic” surfactants. Thus, the concept of the use of “anionic” surfactant is unclear in the lack of specific definitions that would provide some meaningful support for the amended claims. With respect to claims 9 and 33 it is noted that they recite both types of surfactants including anionic and nonionic that are identified as being solely “anionic” by the presently pending claims. Therefore, claims 9 and 33 are also indefinite because at the very least they contain improper Markush groups.

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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1. Claims 1, 2, 6, 11, 13, 14, 21 and 22 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 685 556 (Ghazarian) for the reasons as explained in the prior office action.

Claims are directed to a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin in amounts of about 0.1-6%; 0.0001-1% of surfactant; about 0.5-3% of carbohydrate, about 3-14% of freeze-agent such as glycerol; a buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm. Some claims are further drawn to the use of 90% water in the composition. Some claims are further drawn to incorporation of semen into the semen extender composition. Some claims are/are further drawn to the method of making the semen extender composition by mixing the components of the composition.

EP 0 685 556 (Ghazarian) discloses a semen extender composition which is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, a mixture of Tris and sodium citrate that acts as both surfactant and buffer, carbohydrate such as glucose, fructose or lactose and freeze agent or glycerol (see page 3, lines 4-16). The amounts of ingredients in the cited semen extender composition are within the ranges of the claimed semen extender composition, for example: about 0.6-0.8% of phospholipids or lecithin, about 0.3-0.4% of surfactant or Tris; about 0.5% of total carbohydrate, about 6-7% of freeze-agent or glycerol. Although the cited patent is silent with regard to pH and osmolarity of the semen extender composition and/or solution for semen preservation, the values of pH and osmolarity that are claimed are regular parameters that are commonly used for animal cell culture maintenance and preservation. The cited EP patent also teaches the method of making the semen extender

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composition by mixing the components of the composition. The cited EP patent also teaches incorporation of semen into the semen extender composition (example 3). Thus, the cited patent EP 0 685 556 anticipates the presently claimed invention.

2. Claims 1, 2, 4-6, 11, 13, 14, 21 and 22 as amended remain rejected under 35 U.S.C. 102(e) as being anticipated by US 6,368,786 (Saint-Ramon et al.) for the reasons as explained in the prior office action.

Claims 1, 2, 6, 7, 8, 11, 13, 14, 21 and 22 as explained above. Claims 4 and 5 are further drawn to incorporation of antioxidant or vitamin A into the semen extender composition.

US 6,368,786 teaches a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, surfactant, carbohydrate and buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm, for example: the diluent compositions as disclosed in the tables at col. 3 and 4. The amounts and /or concentrations of ingredients in the cited semen extender composition are within the ranges of the claimed semen extender composition. At least one diluent composition is identical to the composition of the cited above EP 0 685 556 (see example 4 of US'786). Thus, amount of major components are identical as explained above. The diluent composition of the US'786 comprises antioxidant such as vitamin A accompanied by emulsifier Tween 80 (col. 1, lines 49-56). The cited US'786 also teaches the method of making the semen extender composition by mixing the components of the composition. The cited US patent also teaches incorporation of semen into the semen extender composition (example 3).

Thus, the cited patent US 6,368,786 (Saint-Ramon et al.) anticipates the presently claimed invention.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-6, 8-11, 13, 14, 21, 22, 24-26 and 28-31 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 685 556 [Ghazarian] or US 6,368,786 [Saint-Ramon et al] taken with US 3,444,039 [Rajamannan], US 6,130,034 [Aitken], US 6,140,121 [Ellington et al] and the reference by Hellmann et al. [Zuchthg., (1988), 23:33-37; IDS reference] for the reasons as explained in the prior office action and for the reasons below.

Claims are directed to a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin in amounts of about 0.1-6%; 0.0001-1% of surfactant; about 0.5-3% of carbohydrate, about 3-14% of freeze-agent such as glycerol; a buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm. Some claims are further drawn to the use of 90% water in the composition. Some claims are further drawn to incorporation of semen into the semen extender composition. Some claims are/are further drawn to the method of making the semen extender composition by mixing the components of the composition. Some claims are further drawn to the use of surfactant such as sodium lauryl sulfate or Tween 80 in the semen extender composition. Some claims are further drawn to the use of antioxidants such as vitamin A or vitamin E in the semen extender

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composition. Some claims are further drawn to the use of to the use of specific concentrations of anti-oxidant(s) in the semen extender composition.

EP 0 685 556 and/or US 6,368,786 are relied upon as explained above for the disclosure of semen extender compositions. EP 0 685 556 is lacking disclosure about the use of surfactants that are sodium lauryl sulfate and/or Tween 80. EP 0 685 556 is lacking disclosure about the use of antioxidant vitamins. However, US 6,368,786 teaches incorporation of antioxidant vitamin A accompanied by surfactant Tween 80 into the semen extender composition.

Thus, EP 0 685 556 and/or US 6,368,786 are lacking disclosure about the use of particular vitamin such as vitamin E and the use of particular surfactant such as sodium lauryl sulfate.

However, the cited patent US 6,130,034 teaches incorporation of antioxidant such as vitamin E, for example: see col. 1, line 50, as a commonly used and/or regular component in the composition intended for semen transportation and storage (col. 1, line 29). The suggested concentration for anti-oxidant vitamin E is 1mM (col. 1, line 54).

Further, the reference by Hellmann et al. teaches the use of surfactant sodium lauryl sulfate in the composition intended for animal semen preservation (see abstract).

In addition, US 3,444,039 is relied upon to demonstrate that sodium citrate buffering preparation that is commonly used composition intended for semen preservation including semen extender compositions of EP 0 685 556 and/or US 6,368,786 provides for neutral pH of about 6 - 7 and osmolality of about 250-300 mOsm which are regular pH and osmolality parameters for animal cell culture maintenance and preservation (see col. 2, line 6 or see col. 3, line 30 and 44). And the cited US 6,140,121 teaches incorporation of various buffers into compositions intended

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for semen preservation including buffers such as EDTA (col. 19, line 28) or Tris or sodium citrate as well as polyoxyethylene sorbitan which is Tween 80 within the medium M199 in the composition intended for freezing sperm (col. 16, lines 57-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to incorporate ingredients such as various antioxidants and various surfactants into the semen extender composition as required by the presently claimed invention with a reasonable expectation of success in obtaining composition suitable for semen maintenance and/or preservation because these compositions and ingredients have been known and commonly used in the field of semen maintenance and preservation as adequately demonstrated by the cited references in combination. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

### ***Response to Arguments***

Applicants' arguments filed 11/07/2005 have been fully considered and the contents of Declaration by Dr. Richard B. Lomneth filed 4/04/2005 have been reviewed but they are not persuasive for the reasons below.

1. With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by EP 0 685 556 (Ghazarian) applicants argue the present claimed amendment drawn to the use of "anionic" surfactant clearly distinguishes the present invention over the prior art (response page



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8, par. 1). However, the meaning of the term is indefinite because the specification does not clearly redefine the term and the claimed surfactant(s) are not anionic, for example: claims 9 and 10. Moreover, the instant invention as disclosed does not appear to teach the explicit use of anionic surfactant.

Applicants also argue that “TRIS” in the composition of the cited EP is a “buffer” ingredient but not a “surfactant” because it is identified as buffer by the cited EP and because it is commonly used in buffer compositions. Applicants argue that office action does not establish that TRIS would function as a surfactant capable “to reduce crystal formation during freezing” as required for the claimed composition (response page 9). This argument is not found persuasive because, regardless common use of TRIS as a buffering agent, TRIS is also an emulsifying agent as taught by MERCK, for example: see page 1664 of The MERCK INDEX. 1996. 12<sup>th</sup> edition (cited on form PTO 892 mailed 10/29/2004). The emulsifying agents exert an inhibitory effect on freezing denaturation by inhibiting the formation of ice crystal, for example: see col. 3, lines 52-54 of US 6,641,853. Thus, TRIS, as being an emulsifying agent, is reasonably expected to provide for the claimed effect of reducing ice crystal formation in the composition of the cited EP 0 685 556 (Ghazarian).

The presently claimed component (b) is a generic agent having a genetic function. The claimed component (b) is not necessarily one specific ingredient as argued. The cited composition of EP 0 685 556 (Ghazarian) contains various agents that would functions as surfactants and that would also provide function such as “to reduce ice crystal formation during freezing”, for example: glycerol, fructose, glucose, etc. The claimed composition also contains various agents that would have double functions, for example: carbohydrate such as fructose, for

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example, is also a freezing agent; glycerol is a freezing agent and also surfactant. Therefore, the cited composition contains the presently claimed generic component (b) having generic function(s) of surfactant. Thus, the cited composition is not different from the presently claimed composition.

2. With regard to the claim rejection over US 6,368,786 (Saint-Ramon et al.) applicants presented Declaration by Dr. Richard Lomneth (filed 4/04/2005) as evidence to demonstrate a reduction to practice of the instant patent application prior to May 14, 1999 (priority date of US 6,368,786).

In response to the last office action applicants repeatedly argue that BILADYL product does not contain animal-derived component such as egg yolk (response pages 8-9). Yet, the Exhibit B clearly demonstrates that BILADYL contains solutions A and B wherein both solutions A and B contain egg yolk as shown by Exhibit 2 attached to Declaration.

The contents of the Declaration and arguments based thereon were/are not found persuasive because the scope of the showing is different from the scope of instant claims. The claimed invention is drawn to the use of non-animal derived phospholipids. The experiments disclosed on laboratory notebook on pages 1-6 (Exhibit A) describe incorporation of BILADYL product into semen extender compositions and the BILADYL product contains animal derived phospholipids from egg yolk as demonstrated by Exhibit B (product sheet for BILADYL; for example: see col. 1, lines 21-22 for stock solution contents and see col. 2, line 7 for final product contents). The Declaration points out to a particular sample 2 reported on notebook page 6 as being a composition of the instant claims 1 and 21. However, this sample 2 also contains

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BILADYL as disclosed on page 6. Thus, the sample 2 composition contains animal derived phospholipids unlike the composition of the instant claims 1 and 21, drawn to the use of non-animal derived phospholipids. Therefore, the contents of the Declaration and arguments based thereon with regard to priority date(s) are not persuasive.

3. With regard to claim rejection under 35 USC § 103 applicants argue that there is no suggestion to combine references. However, the cited references are in the same field of endeavor (such as compositions intended for semen storage or preservation) and they seek to solve the same problems as the instant application and claims (such as provide for a semen extender composition), and one of skill in the art is free to select components available in the prior art, *In re Winslow*, 151 USPQ 48 (CCPA, 1966).

With regard to EP 0 685 556 [Ghazarian] applicants appear to argue that the cited composition is intended for “nonautonomous microorganisms” outside of their natural environment (response page 10, first par). But this generic term is applied to animal semen as adequately demonstrated in the cited EP particular disclosure that is relied upon in the office action.

With regard to the cited patents US 3,444,039 {Rajamannan}, US 6,130,034 {Aitken} and the reference by Hellmann et al applicants appear to argue (response pages 10-12) that the cited compositions contain animal derived phospholipids from egg yolk. However, these prior art references are relied upon for the teaching about other than phospholipids components as explained above. Moreover, the cited US 6,140,121 [Ellington et al] and US 6,368,786 [Saint-

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Ramon et al] clearly teach exclusion of egg products since the animal products including egg products might carry pathogens. For example: see US 6,140,121 at col. 27, line 16-30; see US 6,368,786 at col.1, lines 22-25. The cited EP 0 685 556 {Ghazarian et al.} and by US 6,368,786 {Saint-Ramon et al.} disclose compositions with non-animal derived phospholipids such as soy lecithin. And the cited US 6,140,121 {Ellington} suggests incorporation of soy lecithin as alternative to egg yolk for the non-egg yolk containing semen extenders (page 27, lines 20-30).

Motivation to combine the prior art teaching can come not only from direct teaching of the prior art, but also the nature of the problem to be solved and/or the knowledge of persons of ordinary skill in the art, *Ruiz v. A.B. Chance Co.* 357 F.3d 1270, 69 USPQ2d 1686 (2004). Further, the examiner recognizes that references cannot be arbitrarily combined that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references, *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. One test for combining references is what the combination of disclosures taken as a whole would suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, the use of components known in the art, and used for their known art specific properties even in different combinations, is considered to be obvious in the absence of evidence to the contrary.

Furthermore, with respect to the contents of the Declaration by Dr. Richard Lomneth (filed 4/04/2005) it is noted that the particular compositions reported in Declaration (4/04/2005) appear to be different from the particular compositions disclosed in the instant specification (pages 17-19) to consider the possibilities of unexpected results, if any. Thus, the advantage that

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is not disclosed in the specification cannot be urged as basis for allowing claims. *In re Lundeborg*, 117 USPQ 190 (CCPA 1958).

No claims are allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

February 13, 2006

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER